

REMARKS

In the Office Action, the Examiner noted that claims 1, 2, 14-10, 12-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7-12, 14-23 of co-pending Application No. 10/823,941. The Examiner's rejections are traversed below.

Double Patenting

The Examiner stated that claims 1, 2, 4-10 and 12-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7-12, 14-23 of copending application 10/823,941 (hereafter application 941). The Examiner further stated that Claims 1, 4, 9, 12, 20 and 21 of the instant invention appear to be identical to claims 1, 5, 11, 14, 22 and 23 of application '941 except for the use of "fluid" instead of "media".

Lastly, the Examiner stated that claims 3 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11 respectively of application '941 and in further view of Leonard (4,913,793).

It is current USPTO policy that a timely filed terminal disclaimer in compliance with 37 CFR 1321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1130(b).

It has been established as of January 1, 1994 that a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Response:

The Applicant has amended independent claims 1, 9, 20 and 21 of the present application which Applicant believes is patentably distinguishable over Leonard. Dependent claims 3 and 11 are dependent upon independent claims 1 and 9, respectively. Furthermore, the Attorney for the Applicant has attached a terminal disclaimer in Exhibit A to address the Examiner's comments. The Applicant believes that the terminal disclaimer overcomes the objection.

CLAIM REJECTIONS -35 USC § 112

The Examiner stated that claims 1-21 are rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Specifically, the Examiner states the independent claims 1, 9, 20 and 21 all refer to the reference element being in a "proximal" position. The Examiner asked "What is the element proximal with to?" The Examiner stated that it is unclear what the proximal position is referred to and clarification is requested.

Response:

The Applicant has amended independent claims 1, 9, 20 and 21 of the present application to state that the reference element is proximal to the antimony sensor as depicted in Figure 1 of the application and as defined on page 8, lines 15-17 which state that "Located proximally from a range of 1-8 centimeters from the proximal end of the antimony sensor 24, and preferably 3-5 centimeters, is a reference element 30."

The Applicant believes that the amended independent claims (1, 9, 20 and 21) now overcome the 35 USC § 112 objection.

CLAIM REJECTIONS -35 USC § 103 - CHRISTNER ET AL. (5,346,606) IN
VIEW OF KLEINBERG (3,742,594)

The Examiner stated that Claims 1 , 2, 5-7, 9, 10, 13-16, 18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christner et al. (USP 5,346,606) in view of Kleinberg (USP 3,742,394). The Examiner stated that Christner discloses a sensor for monitoring pH comprising an outer tubular member 24 and all inner tubular member 16 where said inner tubular member is coaxially and collinearly enclosed within the outer tubular member. (See fig. IA.) The Examiner further stated that Christner discloses a pH sensor enclosed with the inner tubular member and a reference element 22 enclosed within the outer tubular member and located in presumably a proximal position (see 112 rejection above). Additionally, the Examiner stated that Christner further discloses a wick material 12 having one side surrounding and partially engaging the inner tubular member, and that said wick extends from the sensor to the reference element, which it is substantially engaged with. Christner further discloses an ion conducting fluid (i.e. electrolyte) retained within the wick material. The Examiner correctly noted that Christner does not explicitly disclose the use of an antimony sensor for the ion sensor.

The Examiner stated that Kleinberg discloses in an alternate sensor that antimony sensors have a number of advantages over the bulb based electrode of Christner including the ability to 'make smaller, more robust and

more stable' sensors. See col. 1, II, 25-45. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kleinberg for the sensor of Christner so as to make the sensor smaller, more robust and more stable.

Response:

The Applicant has amended independent claims 1, 9, 20 and 21 of the present application to state that the reference element is proximal to the antimony sensor as depicted in Figure 1 of the application and as defined on page 8, lines 15-17 which state that "Located proximally from a range of 1-8 centimeters from the proximal end of the antimony sensor 24, and preferably 3-5 centimeters, is a reference element 30." In addition, the amended independent claims 1, 9, 20 and 21 state that the self-condensing sensor comprises a design that promotes a patient's breath to condense as one or more micro-droplets across the antimony sensor and the reference element. These micro-droplets complete the circuit of the present invention for measuring the pH of the micro-droplets.

Neither Christner nor Kleinberg disclose or claims a device that includes a self-condensing sensor with a design that promotes a patient's breath to condense as one or more micro-droplets across said antimony sensor and said reference element. Additionally, neither Christner nor Kleinberg disclose or claim a device that cooperates with micro-droplets obtained from a patient's breath which functions to complete

the circuit of the present invention and measure the pH of the micro-droplets.

Thus, Applicants respectfully submit that the 1, 9, 20 and 21 of the present application are patentably distinct and are fully distinguishable over Christner et al. in view of Kleinberg. Withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103 - CHRISTNER ET AL. (5,346,606) IN VIEW OF KLEINBERG (3,742,594 AND IN FURTHER VIEW OF LEONARD

The Examiner stated that Claims 3, 4, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christner and Kleinberg as set forth for claims I and 9 above, and in further view of Leonard. The Examiner stated that Christner and Kleinberg set forth all the limitations of these claims, but did not explicitly set forth a cellulose based material or a water based gel for the ion conducting fluid. Leonard teaches in an alternate reference electrode that the addition of cellulose based materials to the ion conducting fluid gels the electrolyte, thereby preventing loss of ion conducting fluid from the reference electrode. See col. 5, 11. 14-23. The Examiner stated that it would have been obvious to one of ordinary skill in the art at the time the invention was being 'made' to utilize the teaching of Leonard for the sensor of Christner and Kleinberg so as to prevent ion conducting fluid loss from the sensor.'

Response:

The dependent claims 3, 4, 11 and 12 are dependent upon the amended independent claims 1 and 9 of the present application. The amended independent claims 1, 9 state that the self-condensing sensor comprises a design that promotes a patient's breath to condense as one or more micro-droplet across the antimony sensor and the reference element. These micro-droplets complete the circuit of the present invention for measuring the pH of the micro-droplets.

Neither Christner, Kleinberg nor Leonard disclose or claims a device that includes self-condensing sensor with a design that promotes a patient's breath to condense as one or more micro-droplets across said antimony sensor and said reference element. In addition, neither Christner, Kleinberg nor Leonard disclose or claim a device that cooperates with micro-droplets obtained from a patient's breath which functions to complete the circuit of the present invention and measure the pH of the micro-droplets.

Thus, Applicants respectfully submit that claims 3, 4, 11 and 12 that are dependent on independent claims 1, and 9 of the present application are patentably distinct and are fully distinguishable over Christner et al. in view of Kleinberg and in further view of Leonard. Withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103 - CHRISTNER ET AL. (5,346,606) IN
VIEW OF KLEINBERG (3,742,594 AND IN FURTHER VIEW OF MOSLEY ET
AL. (6,653,842)

The Examiner stated that Claims 8, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christner and Kleinberg as applied to claims 1 and 9 above, and further in view of Mosley et al. (6,653,842). With respect to claims 8 and 17, the Examiner stated that the references set forth all the limitations of the claim, but did not explicitly disclose the presence of a display which processes information from the sensor. Mosley discloses in an alternate pH sensor that the data should be subsequently processed and displayed for use of the measured data. See col. 10, II. 1-9 and col. 11, II. 5-17. The Examiner stated that it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Mosley for the sensor of Christner and Kleinberg so that the collected data can be converted into an appropriate readable pH number useable by the operator of the sensor. Furthermore, the Examiner stated that with respect to claim 19, Mosley also teaches the use of wireless means of transmitting information. See fig. 5a and col. 13, II. 4-47.

Response:

Claims 8, 17 and 19 are dependent upon the amended independent claims 1, and 9 of the present application. The amended independent claims 1 and 9 state that the self-condensing sensor comprises a design that promotes a patient's breath to condense

as one or more micro-droplets across the antimony sensor and the reference element. These micro-droplets complete the circuit of the present invention for measuring the pH of the micro-droplets.

Neither Christner, Kleinberg nor Mosley disclose or claim a device that includes a self-condensing sensor with a design that promotes a patient's breath to condense as one or more micro-droplets across said antimony sensor and said reference element. In addition, neither Christner, Kleinberg nor Mosley disclose or claim a device that cooperates with micro-droplets condensed from a patient's breath which functions to complete the circuit of the present invention and measure the pH of the micro-droplets.

Thus, Applicants respectfully submit that claims 8, 17, and 19 of the present application are patentably distinct and are fully distinguishable over Christner et al. in view of Kleinberg and in further view of Mosley. Withdrawal of this 103(a) rejection is therefore requested.

Based on the foregoing, Applicant respectfully submits that the application now is in condition for prosecution and allowance. If any matters can be resolved by telephone, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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